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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,176	04/23/2001	Joseph P. Dougherty	13257-00040	2969

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PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,176	DOUGHERTY ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 9-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is 371 national stage filing of PCT/US99/25477, filed October 29, 1999, which claims benefit to provisional application 60/106,533, filed October 31, 1998.

Claims 1-19 are pending.

Election/Restrictions

Applicant's election of Group I, claims 1-3, 7 and 8, in the reply filed on June 16, 2002, paper number 11, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-19 are pending. Claims 4-6 and 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-3, 7 and 8 are under examination as they are drawn to the elected invention of a composition comprising tranduced myeloid committed stem cells and a method of use to express an exogenous nucleic acid sequence.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 4, 2004, paper number 10 has been received and entered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, throughout the specification and particularly on pages 32-34 multiple references are listed. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities:

The disclosure does not contain an abstract. An abstract on a separate page is required. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative. The

abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Appropriate correction is required.

The specification contains sequences that have not been identified with specific SEQ ID NO sequence identifiers. It is noted that a sequence listing is provided, however the sequence disclosed in the specification have not been identified by SEQ ID NO. See for example, page 19.

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Appropriate correction is required.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz DL *et al.* (Exp Hematol. 1994 Aug;22(9):857-65).

Freas-Lutz *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase in a myeloid cells. The cell used by Freas-Lutz *et al.* is the murine leukemia cell line M1 which can differentiate into various cells of the myeloid lineage upon addition of the appropriate factors to the media. The instant specification does not specifically define what a myeloid committed stem cell is, and so is being given the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. The M1 cell line meets this interpretation of a myeloid committed progenitor cell because it is capable of myeloid specific differentiation. Finally, Freas-Lutz *et al.* teach various retroviral constructs using various promoters to analyze the expression and activity of glucocerebrosidase and include the use of the phosphoglycerate gene promoter which is expressed in macrophages, a differentiated myeloid cell.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Migita *et al.* (PNAS 92:12075-12079).

Migita *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase. One of the cell types used by Migita *et al.* are human CD34+ cells (see top of page 12078, for example) which represent a population of cells which have the capacity to differentiate into various cells of the myeloid lineage. As discussed above, the instant specification does not specifically define what a myeloid committed stem cell is, and is being given the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. The CD34+ cells taught by Migita *et al.* meet this interpretation of a myeloid committed progenitor cell because it is capable of myeloid specific differentiation.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Exp. Hematol. (1994) 22:223-230 Xu *et al.* Correction of the enzyme deficiency in hematopoietic cells of Gaucher patients using a clinically acceptable retroviral supernatant transduction protocol.

Bone Marrow Transplant. 1993;11 Suppl 1:124-7. Karlsson S, Correll PH, Xu L. Gene transfer and bone marrow transplantation with special reference to Gaucher's disease.

Each of the above are evidence that at the time of filing various vectors, including retroviral vectors as disclosed in the instant specification, were used to transduce cells of the hematopoietic system to express proteins of interest associated with lysosomal diseases.

US Patent 5,502,176 teaches that various promoters that are functional in myeloid cells were known at the time of filing and used to express a gene of interest in a differentiated myeloid cell.

US Patent 5,246,699 provides further evidence that hematopoietic cells are capable of giving rise to myeloid and lymphoid cell lineages, and that methods to identify or make these cells were known. Further, it teaches the use of hemaotopoetic cells as a means to deliver and express an exogenous polynucleotide.

US Patent 6,207,454, and 6,472,204 each teach improved methods of transducing stem cells, including cells that will differentiate into myeloid lineages.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AU1637